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09/774,558	01/31/2001	Mitchell Anthony DeLong	7997	3530

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EXAMINER

CHANNAVAJJALA, LAKSHMI SARADA

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 04/25/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/774,558	DELONG ET AL.
	Examiner Lakshmi S. Channavajjala	Art Unit 1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 21 March 2002.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-30 is/are pending in the application.

4a) Of the above claim(s) 1,19-28 and 30 is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 2-12,14-18 and 29 is/are rejected.

7) Claim(s) 13 is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. _____.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 21/2.

4) Interview Summary (PTO-413) Paper No(s) _____.

5) Notice of Informal Patent Application (PTO-152)

6) Other: _____

DETAILED ACTION

Receipt of response for restriction requirement (paper # 3), dated 3-21-02, is acknowledged.

Election/Restrictions

Applicant's election without traverse of group II (claims 2-18) and 29 in Paper No. 4 is acknowledged.

Accordingly, claims 2-18 and 29 are further prosecuted on merits. Claims 1, 19-28 and 30 are withdrawn from further consideration.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 2, 3 and 29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Instant claims recite 2-decarboxy-2-phosphinico derivatives and salts, hydrolyzable amides, esters and imides thereof, which is indefinite because applicants have not defined as to different compounds or types of compounds are encompassed by this term. The instant application only mentions salts, hydrolyzable amides, esters and imides of 2-decarboxy-2-phosphinico derivatives of prostaglandins and no other compounds derived from 2-decarboxy-2-phosphinico as such. A clarification and appropriate correction is requested. For the purposes of

examination, examiner interprets 2-decarboxy-2-phosphinico derivatives of the instant claims as 2-decarboxy-2-phosphinico derivatives prostaglandins obtained by coupling of phosphonic acid to the 2-decarboxy prostaglandins (formulae I –III on page 16 of the instant specification).

2. Claim 17 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase “ components C) is present in an amount of 1 to 20% of component C)” is vague and indefinite because it is not clear how the component C) can be 1 to 20% of component C itself, without the knowing as to how much of C is actually present. Does applicants intend to state that the amount of C) is 1 to 20% of the total weight of the composition? For the purposes of prosecution, examiner interprets this limitation as C) is 1 to 20% of the total weight of the composition.

The phrase “such that the amounts of components A), B) and C), combined equal 100%” is indefinite because it is unclear as to what the “combined equal to 100%” is referring to. Is it referring to the total weight of the components of the composition? A clarification and appropriate correction is requested. For the purposes of prosecution, examiner interprets this limitation as amounts of components A), B) and C), together equals to 100% weight of the composition.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 2-10, 12, 14 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by US 4,171,331 to Biddlecom et al (hereafter Biddlecom).

Instant claims are directed to compositions comprising 2-decarboxy-2-phosphinico derivatives of prostaglandins and a carrier. Claim 2 recites the limitation “for treating hair loss”, which is an intended use and carries no patentable distinction. Accordingly, the claim is examined as a composition claim. Claim 15 further defines the carrier as a solvent, emollient, water etc.

Biddlecom discloses 1 and 2-substituted analogues of E, A and F prostaglandins, which includes the instant phosphonic derivatives represented by formula III. In particular, the phosphonic derivatives of prostaglandins are described in col. 7, lines 31-67 and the specific compounds of example V (col. 29, lines 55-67 and col. 30, lines 1-10), compounds of examples VIII and IX (col. 32), compound of example XIII (col. 34) and compound of example XIV (col. 35), all of which read on the instant 2-decarboxy-2-phosphinico derivatives of prostaglandins having hydroxyl groups at C11 position on the pentacyclic ring. Further, Biddlecom discloses preparing solutions of prostaglandin derivatives in water (col. 68, lines 50-53) for testing their

biological activity. Claim 2 recites the limitation “for treating hair loss”, which is an intended use and carries no patentable distinction. Accordingly, the composition of Biddlecom containing phosphonic derivatives of prostaglandin reads on the instant composition claimed. Thus, Biddlecom anticipates the 2-decaroxy-2-phosphinico derivatives of prostaglandins (formula III) of the instant claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 2-10, 12, 14-18 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kende et al (Tetrahedron Letters, 11-19-1999) in view of USPN 6,262,105 to Johnstone.

Instant claims are directed to a composition for the treating hair loss containing 2-decarboxy-2-phosphinico prostaglandin derivatives and a carrier. Claim 16 requires an activity enhancer selected from the group consisting of a hair growth stimulant, a penetration enhancer, and combinations thereof. Claims 17 and 18 require specific amounts of prostaglandin derivative and solvent and activity enhancer. Claim 29 is a mascara composition comprising 2-decarboxy-2-phosphinico derivatives of prostaglandins, a water-insoluble material, and a water-soluble film forming polymer, wax, surfactant, pigment and a solvent.

Kende et al teach the preparation of prostaglandin phosphonic acids through hemolytic halodecarboxylation of **prostaglandin F1 α and F2 α types**. The structures 5 and 11 on pages 8190 and 8191 correspond to the instant 2-decarboxy-2-phosphinico prostaglandins.

In particular, according to instant claims 5 and 6 the variable R2 and R3 could be hydrogen and oxygen respectively. Kende et al teaches prostaglandin derivatives (compounds 5 and 11) with a hydroxyl group, which reads on the instant variables R2 and R3.

Instant claims 3 and 4 define R1 of the phosphonate group as hydrogen, alkyl or ethoxy group etc. The prostaglandin analogue 5 of Kende et al also possesses ethoxy group on the phosphonate group.

Instant claims 3 and 12 require the variable R9 in “OR9” be hydrogen, thus forming hydroxyl groups on the pentacyclic ring. The phosphonic derivatives of Kende et al possess OH groups at the same positions at that of the instant.

Instant claim 8 requires R5 to be 1-5 member atoms and the compounds 5 and 11 of Kende et al also possess a 5 carbon chain. Further, both the compounds 5 and 11 of Kende et al possess a hydroxyl group, which corresponds to C(H)(OH) at R6 position of the instant claims.

Kende et al do not teach any specific use for the phosphonic derivatives of prostaglandins. They also fail to teach the instant carrier, activity enhancer, and amounts of prostaglandin derivatives, specific polymers and wax.

Johnstone teaches a method of enhancing hair growth by administering compositions containing prostaglandins, derivatives or analogues thereof (col. 1, col. 5, lines 6-34). In particular, Johnstone prefers prostaglandins of A2, F2 α and E2 types for hair growth stimulation (col. 5, lines 40-43 and col. 9 through col. 17). Johnstone teaches the prostaglandin F2 α derivatives for hair growth on scalp, eyebrows, eyelids, beard, eye lashes (col. 17, lines 11-15 and lines 58-67).

Accordingly, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to expect hair stimulating activity upon administering phosphonic acid derivatives of prostaglandins (F2 α type) of Kende et al because Johnstone teaches that derivatives and analogues of F2 α prostaglandins in general are useful in the treatment of alopecia or baldness and for terminal hair growth such as for eyelashes, by way increasing the vasodilation and perfusion to hair bulb, increasing protein kinases responsible for trophic activity in the hair follicles and increasing DNA replication and cell division (col. 8, lines 14-59).

Further, Johnstone suggests mixing the prostaglandin derivatives with a vehicle or a carrier and other dermatologically compatible preservatives, surfactants, polymers etc. (col. 17, lines 32-44, and col. 19, lines 50-65). The polymers methylcellulose and polyvinylpyrrolidone taught by Johnstone read on the instant water-soluble and water-insoluble polymers of claim 29. Johnstone does not specifically state film-forming polymer. However, the methylcellulose

polymer of Johnstone is a water-soluble polymer and absent evidence to the contrary, it is the position of the examiner that methylcellulose is capable of forming a film.

Johnstone teaches several oleaginous, water-soluble bases for the compositions such as petrolatum, polyethyleneglycols etc (col. 18, lines 10-21), where the petrolatum reads on the instant wax (of claim 29). Further, Johnstone teaches zinc oxide (example 5, col. 24, lines 34-48), which reads on the pigment of instant claim 29. The various cosmetic components such as viscosity increasing agents, antioxidants etc. (col. 17, lines 32-44, and col. 19, lines 50-65) taught by Johnstone read on the penetration enhancers of claim 16. Therefore, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to incorporate the required carriers and other dermatologically acceptable components (surfactants, water-soluble, water-insoluble polymers, petrolatum, zinc oxide etc.,) of Johnstone in the compositions containing the phosphonic derivatives of prostaglandins (of Kende) with an expectation to impart the desired viscosity, consistency, color etc., to the hair stimulating composition containing the prostaglandin derivatives of Kende et al. Further, with respect to the specific amounts of prostaglandins and other components claimed (claims 17 and 18), Johnstone suggests choosing effective amounts of prostaglandin derivatives for hair stimulation, depending on the derivative employed, frequency of application and desired result, ranging from 0.0000001 to 50% by weight of the dermatological composition. Accordingly, it would have been within the scope of a skilled artisan at the time of the instant invention to optimize the amounts of prostaglandin derivatives depending on the derivative, with an expectation to effectively treat hair (baldness) or improve eyelashes (mascara).

5. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over USPN 4,171,331 to Biddlecom et al (Biddlecom).

Instant claim requires that the terminal R8 group (the chain possessing the variable R8 is known as omega chain of the prostaglandin) is cyclohexyl or aromatic or heteroaromatic group.

Biddlecom, discussed above, teaches prostaglandin analogues, which include the instant phosphonic derivatives (formula III), for their vasodilator, antihypertensive or antithrombotic activities. The general formula of prostaglandins in col. 7 of Biddlecom possesses a terminal group R on the alpha chain, which corresponds to the R8 position of the instant claim. While the examples of phosphonic derivatives of prostaglandins taught by Biddlecom possess only alkyl groups at the R position (see examples in col. 34-col. 36), Biddlecom does not teach any specific compounds having a cyclohexyl or aromatic or heteroaromatic groups, as claimed. However, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to substitute the alkyl group at the terminal R position of the omega chain with a cyclohexyl group because Biddlecom suggests that R could be either an alkyl or a cyclohexyl group (col. 8, lines 16 and claim 1). Thus, one of an ordinary skill in the art would have expected to achieve the same biological activity with prostaglandins having either a cyclohexyl group or an alkyl group at the terminal R position of the prostaglandin omega chain.

Allowable Subject Matter

Claims 13 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter:

Instant claim 13 is directed to phosphonic derivative of prostaglandin, wherein the cyclopentyl moiety of the prostaglandin possesses an NH group at C11 position. The prior art of record teaches phosphonic derivatives of prostaglandins with a hydroxyl group at the C11 position of the cyclopentyl moiety. However, the prior art does not teach or suggest substitution of hydroxyl group at C11 position with NH group.

Accordingly, the composition containing phosphonic derivative of prostaglandin with an NH group at C11 position is novel.

Minor Informalities

In claim 14, applicants define the bond “a” as “as described above”. Examiner notes that the claim 14 is dependent upon claim 3, which already defines the bond “a” and hence is redundant in claim 14. Accordingly, it is suggested that bond limitation is deleted or referred to “as in claim 3”.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 703-308-2438. The examiner can normally be reached on 7.30 AM -4.00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone numbers for the

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organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



Lakshmi S. Channavajjala
Examiner
Art Unit 1615
April 22, 2002